preparation of the reference (WO 98/46215) is a rapidly dissolvable dosage form comprising a') an active ingredient, b') a non-direct compression filler and c') lubricant.

Although both preparations are solid preparations quickly disintegrating in the mouth, their constituent features are clearly distinguished from each other, and their manufacturing techniques are completely different from each other.

First, the filler b') (i.e., excipient such as a saccharide or sugar alcohol) used in the preparation of the reference is limited to a non-direct compression filler which is different from a filler usually used in a conventional preparation. This is different from the preparation of the present invention because the filler is not limited to a non-direct compression filler in the present invention. Fillers include both direct compression fillers and non-direct compression fillers. A "non-direct compression filler" is untreated bulk powder of mannitol, etc. On the other hand, a "direct compression filler" is bulk powder of mannitol, etc. which has been treated so as to impart fluidity and compressibility (see page 17, lines 12 to 15). Then, in general, a "direct compression filler" is used for producing tables by direct compression without granulation. In this respect, the reference says that it is unexpected to use a "non-direct compression filler" and to produce tablets by direct compression (see page 24, lines 12 to 16, etc.).

Second, the mean particle diameter of the saccharide or sugar b) in the present invention is different from that of the non-direct compression filler b') in the reference. As seen from page 17, lines 12 to 26, direct compression fillers have increased particle size to impart fluidity and compressibility as compared with non-direct compression fillers, for example, a minimum of at least about 80% average particle size over 100 microns, in case of direct compression mannitols. On the other hand, the average particle size of the non-direct compression filler used in the reference is about 10 to 80 microns, preferably about 20 to 65 microns. This average particle size is clearly different from the mean particle diameter of 30 to 300 μm in the present invention.

Third, in the present invention, the cellulose compound d) is essential, while it is not essential in the reference. In the present invention, the cellulose compound d) plays an important role to improve the hardness of tablets together with the other excipients. On the other hand, a cellulose compound is not essential though Examples 5 and 7 of the reference disclose the

optional use of a cellulose compound. Further, in the reference, the cellulose compound is used as a wicking agent.

In view of the foregoing, favorable reconsideration and allowance is respectfully solicited.

Respectfully submitted,

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